IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Cefimam DC, 150 mg Intramammary Ointment for Dry Cows

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

PRODUCT SUMMARY

EU Procedure number	IE/V/0320/001/DC
Name, strength and pharmaceutical form	Cefimam DC, 150 mg Intramammary Ointment for Dry Cows
Active substance(s)	Cefquinome (as cefquinome sulfate)
Marketing Authorisation Holder	Norbrook Laboratories (Ireland) Limited, Rossmore Industrial Estate, Monaghan, Ireland
Legal basis of application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of procedure	23rd July 2014
Target species	Cattle (dry cows)
Indication for use	For the treatment of subclinical mastitis at drying off and the prevention of new bacterial infections of the udder during the dry period in the dairy cow caused by the following cefquinome sensitive organisms: *Streptococcus uberis, Streptococcus dysgalactiae, Streptococcus agalactiae, Staphylococcus aureus,* coagulase negative staphylococci.
ATCvet code	QJ51DE90
Concerned Member States	AT, BG, CZ, EE, EL, ES, FR, HR, HU, IT, LT, LV, PL, PT, SI, SK, UK

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using the validated methods and tests, which ensure the consistency of the product released on the market.

It has been shown that the product can be safely used in the target species; the slight reactions observed are indicated in the SPC.

The product is safe for the user, the consumer of foodstuffs from treated amimals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the product was demonstrated according to the claims made in the SPC.

The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and Quantitative Particulars

The product contains 150 mg/syringe of cefquinome (as cefquinome sulfate) and the excipients silica colloidal hydrophobic and liquid paraffin.
The container/closure system consists of high density polyethylene (HDPE) syringes with low density polyethylene (LDPE) plungers and HDPE end caps.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

Process validation data for the manufacturing process has been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is cefquinome (as cefquinome sulfate), an established active substance. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification has been provided.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

D. Control on Intermediate Products

Not applicable.

E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods has been provided.
Batch analytical data from the proposed production site has been provided demonstrating compliance with the specification.

F. Stability

Stability data on the active substance has been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product has been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

This is a 'generic' type application via the decentralised procedure submitted by Norbrook Laboratories Ltd. in accordance with Article 13(1) of Directive 2001/82/EC, as amended. The reference product for this procedure is Cephaguard DC 150mg Intramammary Ointment (VPA 10988/083/001; Virbac SA).

III.A Safety Testing

Pharmacological Studies

The candidate product has the same qualitative and quantitative composition of active ingredient and excipients as the reference veterinary medicinal product, Cephaguard DC 150mg Intramammary Ointment.Based on the similarity of compositions and a series of *in vitro* comparisons, it is accepted that the candidate product can be considered pharmaceutically equivalent (identical) to the reference product and bioequivalence can be assumed. Consequently, it is assumed that, for both products, the safety profile will be the same. In view of the above, the absence of pharmacological studies is justified.

Toxicological Studies

Given that the candidate product can be considered pharmaceutically equivalent (identical) to the reference product and bioequivalence can be assumed, the absence of toxicological studies is justified.

User Safety

A user risk assessment was provided. Given that the candidate product is considered identical to the reference product, it is accepted that the user safety statements agreed for the reference product can be applied to the candidate product.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. The product is not expected to pose a risk to the environment when used in accordance with label recommendations.

Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

III.B Residues Documentation

Residue Studies

No residue depletion studies were conducted.

The candidate product has the same qualitative and quantitative composition of active ingredient and excipients as the reference veterinary medicinal product, Cephaguard DC 150mg Intramammary Ointment.Based on the similarity of

compositions and a series of *in vitro* comparisons, it is accepted that the candidate product can be considered pharmaceutically equivalent (identical) to the reference product and bioequivalence can be assumed. Consequently, it is assumed that, for both products, the residue depletion profile will be the same. In view of the above, the absence of residue studies is justified.

MRLs

MRL status of active substance:

	BOVINE
Muscle	50 microgram/kg
Liver	100 microgram/kg
Kidney	200 microgram/kg
Fat / skin	50 microgram/kg
Milk	20 microgram/kg

Withdrawal Periods

Given that the candidate product is considered identical to the reference product, it is accepted that authorised withdrawal periods for the reference product can be applied to the candidate product.

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies

Pharmacology

The candidate product has the same qualitative and quantitative composition of active ingredient and excipients as the reference veterinary medicinal product, Cephaguard DC 150mg Intramammary Ointment.Based on the similarity of compositions and a series of *in vitro* comparisons, it is accepted that the candidate product can be considered pharmaceutically equivalent (identical) to the reference product and bioequivalence can be assumed.

As this is a generic application according to Article 13, and bioequivalence with a reference product is accepted, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

Tolerance in the Target Species of Animals

Product specific target animal safety data have not been provided.
Given that the test product is considered identical to the reference product, it is accepted that the safety profile of both products will be similar and that the text agreed for sections 4.6 (Adverse reactions) and 4.10 (Overdose) of the authorised reference product can be applied to the test product.

The product, when used as recommended, is expected to be well tolerated in the target animal.

Resistance
Adequate warnings and precautions appear on the product literature.

IV.B Clinical Studies
Given that the candidate product is considered identical to the reference product, and that the conditions of use will be the same, it is accepted that the efficacy profile of both products will be similar. The proposed indications for use and posology are in line with those agreed for the reference product and can be accepted.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

VI. POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the HPRA website.

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

Changes:
None.